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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,793	06/13/2000	Jiangchun Xu	210121.427C15	5630

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/593,793	XU ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/2/2005.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 19,22,61 and 63-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 19,22,61 and 63-65 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-18, 20-21, 23-60 and 62 have been cancelled.

2. Claims 19, 22, 61 and 63-65 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

4. The rejection of claim 61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the Applicant's arguments.

5. The rejection of claims 19, 61 and 63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of U.S. Patent 6,329,505 in view of Hauser and Ladd is withdrawn in view of the terminal disclaimer filed 2/2/2005.

6. The rejection of claims 19, 22, 61 and 63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of U.S. Patent 6,261,562 in view of Hauser and Ladd is withdrawn in view of the terminal disclaimer filed 2/2/2005.

Response to Arguments

7. The rejection of claims 19, 22, 61 and 63 under 35 U.S.C. 103(a) as being unpatentable over Billing-Mendel et al in view of Hauser et al and Ladd et al is maintained.

The response filed 2/2/2005 has been carefully considered, but is deemed not to be persuasive. The response acknowledges that Billing-Mendel describe a polypeptide (SEQ ID NO:36) having identity with residues 299-529 of SEQ ID NO:113 and argues that Billing-Mendel do not teach or suggest that the polypeptide is a human T cell immunogen capable of stimulating a cytotoxic T cell response. The response states that the examiner's rejection is based on an impermissible obvious-to-try standard and argues that the prior art does not suggest that the claimed polypeptide should be combined with a Th1 adjuvant and the secondary references do not provide the requisite motivation to combine the polypeptide of Billing-Mendel with an adjuvant that favors a T cell immune response.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin,

170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969). In this case, Billing Mendel teach a polypeptide (SEQ ID NO:36) that is identical to the instantly claimed polypeptide comprising residues 367-375 of SEQ ID NO:113, which polypeptide is a prostate-specific cancer antigen (see Table 2). Billing-Mendel also teach a method of inducing an immune response comprising administering the polypeptide as well as using the polypeptide for the treatment/therapy of prostate cancer. It would have been prima facie obvious to one of ordinary skill in the art at the time then invention was made to combine the prostate-specific cancer polypeptide of Billing-Mendel with an adjuvant including saponin or MPL because Ladd and Hauser teach formulations comprising an antigen and either saponin or MPL, which "formulations are readily determined by one of ordinary skill in the art" (see Ladd, column 16, lines 55-59). One of ordinary skill in the art would have been motivated to do so because Ladd demonstrates that compositions including saponin enhance the immune response (e.g., see Table 7) and Hauser teaches that compositions comprising MPL have superior immunological properties and MPL is a potent inducer of Th1 when combined with antigen. Thus, there would be an advantage to combining the prostate-specific cancer polypeptide of Billing-Mendel with an adjuvant such as saponin or MPL to increase the immune response to the polypeptide, thereby enhancing the treatment of prostate cancer. The strongest rationale or motivation for combining references is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning

based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144. In response to applicant's argument that the combination is based on an obvious-to-try standard, both Ladd and Hauser teach that the inclusion of either saponin or MPL effectively increased antigen immunogenicity and enhanced the immune response against antigen. Thus, one of ordinary skill in the art would have had a reasonable expectation of success of increasing the immunogenicity of the prostate-specific cancer polypeptide of Billing-Mendel by combining the polypeptide with saponin or MPL as taught by Ladd and Hauser for increased therapeutic benefit of prostate cancer. Applicant is reminded that there is no requirement that the prior art provide the same reason as applicant to make the claimed invention (MPEP 2144).

In response to Applicant's argument that the prior art does not teach that the claimed polypeptide is a T cell immunogen, it is reiterated that applicant's discovery of a previously unappreciated property of the polypeptide of Billing-Mendel, does not render the polypeptide of Billing-Mendel patentably new to discover. Billing Mendel teach a polypeptide that is identical to the instantly claimed polypeptide comprising residues 367-375 of SEQ ID NO:113. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses

and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

8. The rejection of claims 64 and 65 under 35 U.S.C. 103(a) as being unpatentable over Billing-Mendel et al in view of Mincheff et al and Salgaller et al is maintained.

The response filed 2/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that there is nothing in the cited prior art suggesting that an antigen presenting cell expressing the polypeptide comprising the T cell epitope of amino acid residues 367-375 of SEQ ID NO:113, which stimulates a human cytotoxic T lymphocyte response specific for SEQ ID NO:113, should be combined with an adjuvant which induces a predominantly Th1-type immune response. The response also argues that one would not be motivated to make such a composition without knowledge that the polypeptide is capable of eliciting an effective human T cell response when expressed in an antigen-presenting cell and any motivation is impermissibly founded on applicant's disclosure. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*,

443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case Mincheff teach a method of treating prostate cancer patients, wherein dendritic cells are transfected with a nucleic acid encoding a prostate cancer antigen and infused back into the prostate cancer patient, where they stimulate autologous T cells and Salgaller teach that the co-administration of GM-CSF as an adjuvant with dendritic cells pulsed with prostate cancer peptides enhances cellular immunity. Thus, from the combined teachings of Mincheff and Salgaller, it was known at the time the invention was made that dendritic cells transfected with a nucleic acid encoding a prostate cancer antigen, effectively stimulates T cells and co-administration of GM-CSF with said dendritic cells enhances cellular immunity. Billing-Mendel teach a prostate-specific cancer polypeptide comprising amino acid residues 367-375 of SEQ ID NO:113 as well as the nucleic acid encoding this polypeptide. Thus, it would have been prima facie obvious at the time the invention was made to have transfected dendritic cells with the nucleic acid encoding the prostate-specific cancer polypeptide of Billing-Mendel and co-administer GM-CSF with the transfected dendritic cells for therapeutic benefit in prostate cancer patients. One of ordinary skill in the art would have had a reasonable expectation of success because Mincheff demonstrates that transfecting dendritic cells with a nucleic acid encoding a prostate cancer antigen stimulates autologous T cells and Salgaller demonstrate that co-administration of GM-CSF with dendritic cells pulsed with prostate cancer peptides effectively enhances cellular immunity. Therefore, the motivation and reasonable expectation of success are obtained only from knowledge which was within the

level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned from applicant's disclosure.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Th1-type immune response) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Although applicant has apparently discovered that the claimed polypeptide comprises a T cell epitope of amino acids 367-375 of SEQ ID NO:113, artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient, which is inherently contained in the prior art.

Conclusions

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER